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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,646	09/18/2001	Seth A. Foerster	END-777	8823

34263 7590 04/21/2006

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EXAMINER
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MANTIS MERCADER, ELENI M

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/954,646		FOERSTER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Eleni Mantis Mercader		3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 46-51,55-60,62 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 46-51,55-60,62 and 65-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/31/2006</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/31/2006 has been entered.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 46-51, 55, 56-60, 62, and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al.'936 of record in view of Kandany'613 (US Patent No. 5,562,613) and Shiber'540 (US Patent No. 5,195,540).

Campbell et al.'936 teach an introducer for inserting a marker element into a particular tissue element having an introducer with a tube having a lumen an axial opening at the proximal end of the tube (see in Figure 10, plunger 18), a side exit port at the distal end of the port (see Figure 15 below, element 22) with at least one discrete marker positioned in the tube (see Figure 18 showing a marker cartridge assembly for delivering markers at the area of interest) and a shaft extending from the axial opening and ejecting the marker from the side exit port by the

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application of compressive force (referring to the plunger 18 pushing the marker 30; see col. 4, lines 24-58) such that no marker element extends outside the body (referring to subcutaneous penetration; see col. 1, lines 33-43).

Campbell et al.'936 do not teach a closed distal end and a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube.

In the same field of endeavor, Kaldany'613 teaches a closed distal end and a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube for the introduction of pellets of interest (see Figure 7 and respective specification description in col. 5, lines 22-34).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Campbell et al.'936 and incorporated the teaching of Kaldany'613 in order to alter the end of the catheter to have a closed distal end with a side exit port defining a plane, the plane being parallel to the longitudinal axis of the tube, wherein the side exit port is located adjacent a distal end of said tube in order to enable the physician to advance the marker at the area of interest with greater precision once the side port has been aligned with the tissue of interest by allowing for a simple unidirectional handed motion (see for motivation to combine Kaldany'613, col. 2, lines 45-49).

Campbell et al.'936 further teaches a plurality of markers capable of being introduced (see col. 7, line 65- col. 8, line 16).

The use of expandable markers to further enhance attachment to the tissue of interest while allowing for easier transfer through the lumen and the variety of materials used for such

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markers as long as they are biocompatible are well known functional equivalents to skilled artisans.

Campbell et al.'936 in view of Kandany'613 teach all the elements of the current invention except for the use of an imaging system to guide the insertion of a marker such as x-ray or ultrasound or making the marker radio-opaque.

In the same field of endeavor, Shiber'540 teaches an imaging system to guide the insertion of a marker such as x-ray or ultrasound (see col. 1, lines 4-23; and especially lines 20-23). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Campbell et al.'936 in view of Kandany'613 and incorporated the teaching of Shiber'540 because if the area of interest for insertion of the marker (spiral wire marking the tissue) is human tissue such as breast imaging is necessitated to avoid further trauma to the patient by accurately guiding the marker at the location of interest (see for motivation to combine in Shiber'540 col. 2, lines 21-26).

In the same field of endeavor, Shiber'540 teaches making the marker radio-opaque or of any material allowing visualization by the imaging modality of interest (see col. 2, lines 7-14).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Campbell et al.'936 in view of Kandany'613 and incorporated the teaching of Shiber'540 because that would increase the visibility of the guided procedure and accurate visualization of the positioning of the marker at the area of interest.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM